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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,574	03/17/2004	James J. Schmidt	003/289/SAP	3751

7590 07/28/2004

ATTN: MCMR-JA (Elizabeth Arwine- PATENT ATTY)
U.S. Army Medical Research and Material Command
Staff Judge Advocate Office
504 Scott Street
Fort Detrick, MD 21702-5012

EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,574	SCHMIDT ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-54 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1-3, 16, 17, 20-22, 39 and 40, drawn to a clostridial neurotoxin substrate containing a signal moiety on one side of the cleavage site, and a moiety that quenches the signal on the other side of the cleavage site; or a kit containing the substrate and the clostridial neurotoxin standard, wherein the clostridial neurotoxin is botulinum neurotoxin serotype A, classified in class 514, subclass 12, and class 530, subclass 300.

II. Claims 1, 4, 5, 16, 18, 20, 23, 24, 39 and 41, drawn to a clostridial neurotoxin substrate containing a signal moiety on one side of the cleavage site, and a moiety that quenches the signal on the other side of the cleavage site; or a kit containing the substrate and the clostridial neurotoxin standard, wherein the clostridial neurotoxin is botulinum neurotoxin serotype B, classified in class 514, subclass 12, and class 530, subclass 300.

III. Claims 1, 6, 7, 16, 19, 20, 25, 26, 39 and 42, drawn to a clostridial neurotoxin substrate containing a signal moiety on one side of the cleavage site, and a moiety that quenches the signal on the other side of the cleavage site; or a kit containing the substrate and the clostridial neurotoxin standard, wherein the clostridial neurotoxin is botulinum neurotoxin serotype D or F, classified in class 514, subclass 12, and class 530, subclass 300.

IV. Claims 1, 16, 20, 27, 28, 39 and 43, drawn to a clostridial neurotoxin substrate containing a signal moiety on one side of the cleavage site, and a moiety

that quenches the signal on the other side of the cleavage site; or a kit containing the substrate and the clostridial neurotoxin standard, wherein the clostridial neurotoxin is botulinum neurotoxin serotype E, classified in class 514, subclass 12, and class 530, subclass 300.

V. Claims 8-11 and 29-32, drawn to a method for detecting the presence of clostridial neurotoxin proteolytic activity or measuring the concentration of clostridial neurotoxin in a sample using the clostridial neurotoxin substrate, wherein the clostridial neurotoxin is botulinum neurotoxin serotype A, classified in class 514, subclass 12, and class 435, subclass 7.1.

VI. Claims 8, 9, 12, 13, 29, 30, 33 and 34, drawn to a method for detecting the presence of clostridial neurotoxin proteolytic activity or measuring the concentration of clostridial neurotoxin in a sample using the clostridial neurotoxin substrate, wherein the clostridial neurotoxin is botulinum neurotoxin serotype B, classified in class 514, subclass 12, and class 435, subclass 7.1.

VII. Claims 8, 9, 14, 15, 29, 30, 35 and 36, drawn to a method for detecting the presence of clostridial neurotoxin proteolytic activity or measuring the concentration of clostridial neurotoxin in a sample using the clostridial neurotoxin substrate, wherein the clostridial neurotoxin is botulinum neurotoxin serotype D or F, classified in class 514, subclass 12, and class 435, subclass 7.1.

VIII. Claims 8, 9, 29, 30, 37 and 38, drawn to a method for detecting the presence of clostridial neurotoxin proteolytic activity or measuring the concentration of clostridial neurotoxin in a sample using the clostridial neurotoxin

substrate, wherein the clostridial neurotoxin is botulinum neurotoxin serotype E, classified in class 514, subclass 12, and class 435, subclass 7.1.

IX. Claims 44 and 45, drawn to a method for identifying inhibitors or enhancers of proteolysis activity of a clostridia neurotoxin using the clostridia neurotoxin substrate, wherein the clostridia neurotoxin is botulinum neurotoxin serotype A, classified in class 514, subclass 12, and class 435, subclass 7.1.

X. Claims 44 and 46, drawn to a method for identifying inhibitors or enhancers of proteolysis activity of a clostridia neurotoxin using the clostridia neurotoxin substrate, wherein the clostridia neurotoxin is botulinum neurotoxin serotype B, classified in class 514, subclass 12, and class 435, subclass 7.1.

XI. Claims 44 and 47, drawn to a method for identifying inhibitors or enhancers of proteolysis activity of a clostridia neurotoxin using the clostridia neurotoxin substrate, wherein the clostridia neurotoxin is botulinum neurotoxin serotype D or F, classified in class 514, subclass 12, and class 435, subclass 7.1.

XII. Claims 44 and 48, drawn to a method for identifying inhibitors or enhancers of proteolytic activity of a clostridial neurotoxin using the clostridial neurotoxin substrate, wherein the clostridial neurotoxin is botulinum neurotoxin serotype E, classified in class 514, subclass 12, and class 435, subclass 7.1.

XIII. Claims 49-54, drawn to a method or kit for identifying a serotype of a clostridial neurotoxin in a sample suspected of containing a neurotoxin, using antibodies against a clostridial neurotoxin and a clostridial neurotoxin peptide substrate, classified in class 514, subclass 12, and class 530, subclass 387.1.

2. The inventions are distinct, each from the other because of the following reasons:

The products of Inventions I-IV and XIII are patentably distinct from each other because each clostridial neurotoxin substrate, which contains different amino acid sequence, has different chemical and physical properties, and is used for detecting a different clostridial neurotoxin, is patentably distinct; and each kit, which contains different materials such as different clostridial neurotoxin substrate, or, different clostridial neurotoxin substrate and antibody specific for different clostridial neurotoxin, is patentably distinct.

The product of Invention I and the methods of Inventions V and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions V and IX are alternative processes of use of the product of Invention I.

The product of Invention II and the methods of Inventions VI and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions VI and X are alternative processes of use of the product of Invention II.

The product of Invention III and the methods of Inventions VII and XI are related as product and process of use. The inventions can be shown to be distinct if either or

both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions VII and XI are alternative processes of use of the product of Invention III.

The product of Invention IV and the methods of Inventions VIII and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions VIII and XII are alternative processes of use of the product of Invention IV.

The product of Invention I is distinct from the methods of Inventions VI-VIII and X-XIII because the product of Invention I cannot be made by nor used in the methods of Inventions VI-VIII and X-XIII.

The product of Invention II is distinct from the methods of Inventions V, VII, VIII, IX, and XI-XIII because the product of Invention I cannot be made by nor used in the methods of Inventions V, VII, VIII, IX, and XI-XIII.

The product of Invention III is distinct from the methods of Inventions V, VI, VIII, IX, X, XII and XIII because the product of Invention I cannot be made by nor used in the methods of Inventions V, VI, VIII, IX, X, XII and XIII.

The product of Invention IV is distinct from the methods of Inventions V-VII, IX-XI and XIII because the product of Invention I cannot be made by nor used in the methods of Inventions V-VII, IX-XI and XIII.

The methods of Inventions V-XIII are distinct from each other because they have different method steps, use different materials and produce different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, and because inventions I-XIII require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise**

include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK
July 24, 2004